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Request for grant of a patent

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1. Your reference — PK/03029GB

2. Patent application number *(The Patent Office will fill in this part)* — 0302459.3 — 03 FEB 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

University College London
Gower Street
London
WC1E 6BT

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation — United Kingdom

4. Title of the invention — A surgical Kit for Hemiarthroplasty Hip Replacement

5. Name of your agent *(if you have one)*

~~Brookes Batchellor~~ SOMMERVILLE + RUSHTON LTD

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

~~102-108 Clerkenwell Road, London, EC1M 5SA~~ GROSVENOR ROAD, ST ALBANS HERTS AL1 3AW

Patents ADP number *(if you know it)* ~~811601~~ 8112241001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*
	151100 1	

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Yes

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9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	0
Description	4
Claim (s)	2
Abstract	1
Drawing (s)	1 + 1

10. If you are also filing any of the following, state how many against each item.

Priority documents	0
Translations of priority documents	0
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	0
Request for preliminary examination and search *(Patents Form 9/77)*	1
Request for substantive examination *(Patents Form 10/77)*	0
Any other documents *(please specify)*	0

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 3/12/2003

12. Name and daytime telephone number of person to contact in the United Kingdom: Paul G Kemp 020 7253 1563

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A Surgical Kit for Hemiarthroplasty Hip Replacement

The present invention is concerned with a kit of parts comprising in particular a femoral head and reamer provided for hip replacement.

In conventional hip replacement surgery the surgeon replaces the femoral head and reams out the acetabulum prior to insertion of a prosthetic acetabulum. The prosthetic femoral head, stem, acetabulum and reamer are all provided as a kit by an implant supplier, such as the applicant, in accordance with a set of patient specification determined by the surgeon. The reamer is designed to ream out exactly sufficient material from the acetabulum to fit the replacement prosthetic acetabulum. This form of hip replacement is known as total hip replacement. In some cases the hip is repaired by hemiarthroplasty in which the femoral head only is replaced. In such cases the natural femoral head is replaced in much the same way as with total hip replacement, however, the acetabulum is left substantially untouched with the natural cartilage still in place. Therefore the surgical kit for hemiarthroplasty does not include a reamer or acetabulum.

The prosthetic acetabulum may be said to have a male side which is closely received into the socket formed by the reamer and a female side which provides the socket into which the prosthetic femoral head directly and closely fits. The reamer is therefore sized to complement the male side of the prosthetic acetabulum.

In use the prosthetic acetabulum provides the bearing surface for the femoral head. However, being inert, the bearing surfaces of the acetabulum wear during use until the replacement hip joint needs repair. It is desirable to defer or avoid this problem completely because the repair process involves a major surgical procedure with the associated discomfort and risk to the patient.

The present invention aims to alleviate this problem and accordingly provides a surgical kit for hip replacement comprising:

a prosthetic femoral head and a reamer,

said reamer being adapted to ream a socket into an acetabulum until the cancellous bone is exposed,

the femoral head having a size and shape complementary to the reamer such that the femoral head can be fitted closely and directly into a reamed acetabulum whereby liquid between the femoral head and the socket will be subjected to a hydrostatic pressure in the range of 0.01-5Mpa.

The steps of the surgical procedure comprise first identifying certain characteristics of the patient which may include weight, the dimensions of the natural femur and pelvis. Using known methods such as those developed by G. Bergman, the implant manufacturer determines the size and shape of femoral head required which will result in any liquid between the femoral head and a closely matching socket being subject to a pressure of between 0.01 and 5 MPa. A femoral head and matching reamer are then produced for the kit. The dimensions of the reamer are chosen to closely match the dimensions of the femoral head. In the surgical procedure the reamer supplied in the kit is used by the surgeon to ream out the cartilage lining the acetabulum and then the cortical bone until the underlying cancellous bone is exposed and bleeding. The liquid bleeding from the cortical bone includes stem cells. The femoral head is secured to a femoral stem socketed into the patient's natural femur in a substantially conventional way and the femoral head socketed into the reamed acetabulum. The liquid is thus subject to a hydrostatic pressure in the range of 0.01-5MPa., preferably in the range of 0.5-2MPa and more preferably near to 2MPa. The stem cells within the liquid are thus encouraged to form chondrocites which grow into cartilage lying on the subchondrial bone which provides a natural active bearing surface for the femoral head.

In order to further promote the formation of cartilage spacers may be provided to separate the surface of the femoral head and the reamed acetabulum. The spacers may be provided on the surface of the prosthetic femoral head and may be formed of material

which is resorbable to provide a temporary bearing surface which is resorbed as the cartilage develops.

The material or materials from which the femoral head and or spacers are formed may be compliant, have different moduli, and different frictional characteristics to control the stresses and friction on the reamed bone surface. The components of the femoral head may also include means to deliver growth factors to encourage the formation of cartilage. More particularly the spacers may deliver growth factors as they are resorbed.

A surgical kit for hemiarthroplasty hip replacement embodying the present invention will now be described, by way of example only, with reference to the accompanying illustrative figures, in which:

Figure 1 illustrates a femoral head, and

Figure 2 illustrates a reamer.

Figure 1 illustrates a prosthetic femoral head 1 which may be integral with a femoral stem or adapted for fitting to a femoral stem as is known. A femoral shaft 2 extends from the femoral head 1. The femoral head 1 is part spherical and provided with spacers 3 located at intervals across its surface to provide a temporary bearing surface. The spacers 3 are formed from a material which is gradually resorbed and gradually dispenses growth factors.

A reamer is shown in figure 2 and has a part spherical head 4. Abrading elements 5 of substantially conventional design are dispersed across the spherical surface of the reamer so that in use the reamer produces a socket in an acetabulum corresponding in size and shape to the envelope indicated by the outer dotted line 6. As can be seen in figure 1 the outer dotted line 6 also forms an envelope around the bearing surface provided temporarily by the spacers 3 formed on the surface of the femoral head 1. The size of the femoral head 1 is determined via reference to the characteristics such as the weight of the patient so that the pressure of liquid present between the femoral head and the socket formed in the acetabulum by the reamer is in

the range between 0.01-5MPa, and preferably close to 2MPa, for example in the range between 0.5-2MPa.

The femoral head fits directly into the socket produced by the reamer without any intervening, permanent liner. However, the material from which the femoral head is made may be compliant to control the hydrostatic pressure.

Claims

1. A surgical kit for hip replacement comprising:

a prosthetic femoral head and a reamer,

said reamer being adapted to ream a socket into an acetabulum until the cancellous bone is exposed,

the femoral head having a size and shape complementary to the reamer such that the femoral head can be fitted closely and directly into a reamed acetabulum whereby liquid between the femoral head and the socket will be subjected to a hydrostatic pressure in the range of 0.01-5Mpa.

2. A surgical kit according to claim 1 wherein the hydrostatic pressure is in the range 0.5-2MPa.

3. A surgical kit according to claim 2 wherein the hydrostatic pressure is 2MPa.

4. A surgical kit according to claim 1 wherein spacers are provided to space the surface of the femoral head and the reamed acetabulum.

5. A surgical kit according to claim 2 wherein the spacers are of resorbable material.

6. A surgical kit according to any one of the preceding claims wherein the surface of the femoral head is formed from a variety of materials adapted to deform and so sustain the hydrostatic pressure.

7. A surgical kit according to any one of the preceding claims wherein the femoral head is provided with means to deliver growth factors to the liquid.

8. A surgical kit according to claim 1 and as herein described with reference to the accompanying figures.

Abstract

The invention concerns a surgical kit provided for performing a hip hemiarthroplasty, in which a femoral head is fitted directly into a socket reamed into the acetabular without any permanent liner or prosthetic acetabular being implanted. The reamer is used to ream out the acetabular until cancellous bone is exposed so that it bleeds liquid containing stem cells. By selecting the size of the femoral head in accordance with the characteristics of the patient, the pressure imposed on the liquid is in the range between 0.5 and 2MPa. This causes the stem cells to produce new cartilage between the bone and femoral head.

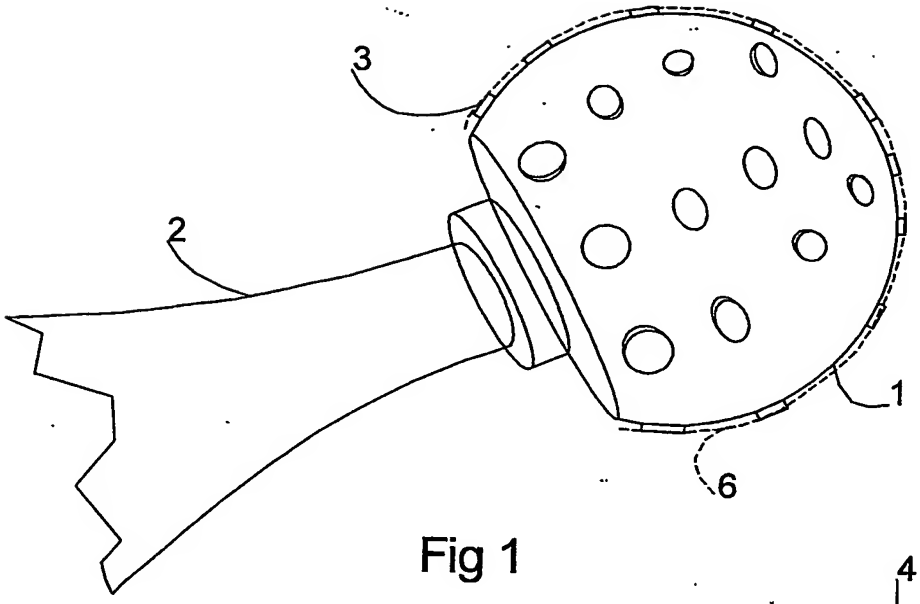

Fig 1

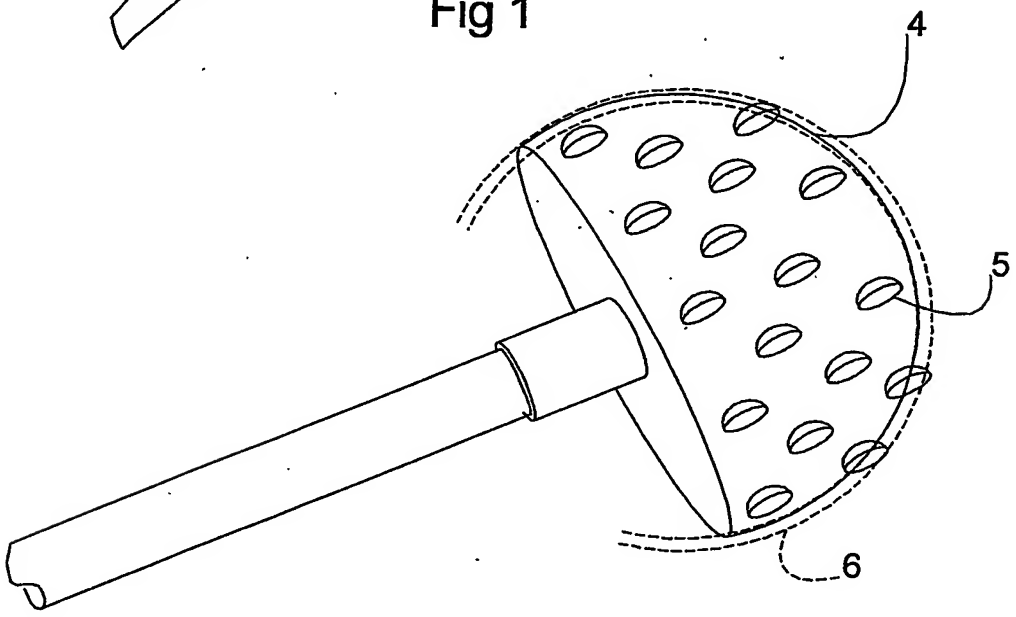

Fig 2